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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/622,816      | 07/17/2001  | Guy Weinberg         | 27611 35364         | 4693             |

7590

05/17/2005

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/622,816

Applicant(s)

WEINBERG ET AL.

Examiner

Gollamudi S. Kishore, Ph.D

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 30-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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**DETAILED ACTION**

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-29 are, drawn to a lipid emulsion.

Group II, claim(s) 30-35 are, drawn to a delivery device.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the composition in Group I is drawn to a specific emulsion composition and the in the delivery device of Group I the emulsion container is not a part of the delivery device; the delivery device contains a vented spike which can be connected to any emulsion container or any other composition meant for delivery.

3. During a telephone conversation with Jim Napoli on 5-12-05 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-29.

Affirmation of this election must be made by applicant in replying to this Office action.

Claims 30-35 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The distinction between 'emulsifier' in claim 1, 'surfactant' in claim 2 and 'polyethoxylated hydrocarbons' or 'aliphatic fatty acids recited as tonicity modifiers in claim 20 is unclear. Surfactants are emulsifiers and polyethoxylated hydrocarbons and fatty acids are surfactants.

Claim 28 is a method claim reciting 'method of claim 21'; claim 21 is a composition claim and not a method claim. Similar is the case with claim 29.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Katz (5,089,268).

Katz discloses sterile lipid emulsions containing soybean oil (1-30 %), egg phosphatides, 1-4% (which include lecithin), omega 3 and 6 fatty acids, glycerol (up to 2.25 %, a medicament and water (abstract, columns 2-3 and claims). Since phosphatides are surfactants and since instant claim 23 does not recite a specific surfactant, the reference meets the requirements of said claim 23. On col. 3, lines 14-15 Katz indicates that the emulsion is filtered through 0.45 micron filter and therefore, in the absence of showing otherwise, it is the examiner's position that Katz's emulsion has instant particle sizes.

9. Claims 1-24 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 2050 799.

GB discloses lipid emulsions containing soybean oil (5-50 %), egg yolk phospholipids in 1/4 -1/25 ratio to the soybean oil, fatty acids, glycerol, cholesterol and water (abstract, page 1, examples and claims). As pointed out above, since phospholipids are surfactants and since instant claim 23 does not recite a specific surfactant, the reference meets the requirements of said claim 23.

10. Claims 1-26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by applicant's statements of prior art.

Applicant on page 5. line 24 of the specification indicates that the emulsion claimed is available commercially under the name Intralipid since 1975).

11. Claims 1-4, 6 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Asher (4,183,918).

Asher discloses lipid emulsions containing either mineral oil or a vegetable oil, a surfactant, 1-5 % (emulsifier), sucrose (tonicity modifier) for the removal of toxic agents (abstract, col. 3, line 47 through col. 5, line 57, Examples and claims).

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asher cited above by itself or in combination with Takami (4,323,563) and Hope (6,139,871).

The teachings of Asher have been discussed above. What is lacking in Asher is the administration of the emulsion intravenously to remove the toxic material in circulation. However, it would have been obvious to one of ordinary skill in the art to administer Asher's emulsions intravenously if the toxins to be removed are in circulation since Asher has shown the emulsion's ability to remove the toxins. One of ordinary skill in the art would be motivated to use Asher's emulsions intravenously, with a reasonable expectation of success, because the reference of Takami shows that fat emulsions can be injected intravenously (see abstract) and that of Hope shows that emulsions such as


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liposomal emulsions could be administered intravenously to remove cholesterol from blood (example 1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK